MAY 19 2014

510(k) Summary
Gyrus ACMI, Inc.
THUNDERBEAT
TB-0535PC/0545PC/0510IC/0520IC/0535IC/0545IC

General Information

Applicant:	OLYMPUS MEDICAL SYSTEMS CORP. 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507 Phone: (+81) 42-642-2694 Fax: (+81) 42-642-2307
Establishment Registration Number:	8010047
Manufacturer:	Aomori Olympus 248-1 Okkonoki 2-chome Kuroishi-shi, Aomori, Japan 036-0367 Phone: (+81) 172-52-8543 Fax: (+81) 172-52-8515
Establishment Registration Number:	9614641
510(k) Submitter:	Gyrus ACMI, Inc. 136 Turnpike Rd. Southborough, MA 01772-2104
Establishment Registration Number:	3003790304
Contact Person:	Graham Baillie Manager, Regulatory Affairs
Date Prepared:	May 5, 2014

Device Identification

Classification Name:	Electrosurgical cutting and coagulation device and accessories
Regulation Number:	21 CFR 878.4400
Product Code(s):	GEI, LFL
Regulatory Class:	II, Unclassified
Review Panel:	General & Plastic Surgery
Generic/Common Name:	Ultrasonic and electrosurgical devices
Trade Name:	THUNDERBEAT Hand Instruments

Model Name	Device Name
TB-0545PC	THUNDERBEAT 5mm, 45cm, Pistol Grip
TB-0535PC	THUNDERBEAT 5mm, 35cm, Pistol Grip
TB-0545IC	THUNDERBEAT 5mm, 45cm, Inline Grip
TB-0535IC	THUNDERBEAT 5mm, 35cm, Inline Grip
TB-0520IC	THUNDERBEAT 5mm, 20cm, Inline Grip
TB-0510IC	THUNDERBEAT 5mm, 10cm, Inline Grip

Predicate Devices

Olympus Medical Systems Corp. THUNDERBEAT TB-0535PC, 0545PC, 0510IC, 0520IC, 0535IC and 0545IC K111202

Covidien LigaSure Small Jaw K113572

Product Description

The THUNDERBEAT hand instruments are intended to be used with the Ultrasonic Generator (USG-400), the Electrosurgical Generator (ESG-400), and the THUNDERBEAT Transducer, (TD-TB400).

The THUNDERBEAT hand instruments are provided as sterile, single use devices. These are functional devices capable of vessel sealing & cutting, tissue coagulating & cutting, grasping, dissecting. These instruments have been designed to seal and cut vessels up to and including 7 mm in diameter, tissue bundles, and lymphatics for open, laparoscopic, open ENT and endoscopic procedures in surgery.

Technological Characteristics

The THUNDERBEAT activates combined HF Bipolar (FineCoag) output and Ultrasonic output [Seal and Cut mode] simultaneously while grasping a tissue or a vessel between the Probe and the Grasping section.

The THUNDERBEAT also performs the HF Bipolar (HardCoag) output [Seal mode]. Those outputs lead to sealing and cutting/sealing of vessels or coagulating and cutting soft tissue.
The hand switches provided on the grip handle enable those output operations. However, the technological features of the subject devices are identical to the predicate (K111202) such as the shaft length, shaft rotation, and shaft diameter.

Material

The patient contacting materials are well established and identical to the predicate devices cleared under K111202. Full biocompatibility testing on all patient contacting surfaces has been performed in compliance to the relevant requirements of ISO-10993.

Intended Uses

The purpose of this submission is to demonstrate equivalence to predicate devices and to expand the Indication for Use for the existing (subject) TB-0535PC/0545PC/0535IC/0545IC/0510IC/0520IC. The additional indications appear as bolded text under the Intended Use section below.

THUNDERBEAT TB-0535PC/0545PC/0535IC/0545IC

The THUNDERBEAT hand instruments are intended to be used with the Ultrasonic Generator (USG-400), the Electrosurgical Generator (ESG-400), and the THUNDERBEAT Transducer, (TD-TB400).

Seal & Cut mode:
The THUNDERBEAT hand instruments when used in combination with the Seal & Cut mode are indicated for open, laparoscopic (including single-site surgery) general surgery and gynecological surgery (including urologic, thoracic, plastic and reconstructive, bowel resections, cholecystectomies, Nissen fundoplication, adhesiolysis, oophorectomy, hysterectomies (both vaginal assisted and abdominal) etc) and endoscopic surgery or in any procedure in which cutting, vessel ligation (sealing and cutting), coagulation, grasping, and dissection is performed. These devices have been designed to seal and cut vessels (up to and including 7 mm in diameter), **tissue bundles, and lymphatics.**

Seal mode:
The THUNDERBEAT hand instruments when used in combination with the Seal mode are indicated for open, laparoscopic (including single-site surgery) general surgery and gynecological surgery (including urologic, thoracic, plastic and reconstructive, bowel resections, cholecystectomies, Nissen fundoplication, adhesiolysis, oophorectomy, hysterectomies (both vaginal assisted and abdominal) etc), and endoscopic surgery or in any procedure in which vessel sealing, coagulation, grasping is performed. These devices have been designed to seal vessels (up to and including 7 mm in diameter), **tissue bundles, and lymphatics**.

The THUNDERBEAT hand instruments have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

THUNDERBEAT TB-0510IC/0520IC

The THUNDERBEAT hand instruments are intended to be used with the Ultrasonic Generator (USG-400), the Electrosurgical Generator (ESG-400), and the THUNDERBEAT Transducer, (TD-TB400).

Seal & Cut mode:
The THUNDERBEAT hand instruments when used in combination with the Seal & Cut mode are indicated for open, laparoscopic (including single-site surgery) general surgery and gynecological surgery (including urologic, thoracic, plastic and reconstructive, bowel resections, cholecystectomies, Nissen fundoplication, adhesiolysis, oophorectomy, hysterectomies (both vaginal assisted and abdominal) etc) and endoscopic surgery or in any procedure in which cutting, vessel ligation (sealing and cutting), coagulation, grasping, and dissection is performed. These devices have been designed to seal and cut vessels (up to and including 7 mm in diameter), **tissue bundles, and lymphatics**.

This mode is also indicated for open ENT procedures in adults for ligation (sealing and cutting) of vessels, lymphatics and tissue bundles away from unintended thermally sensitive structures.

Seal mode:
The THUNDERBEAT hand instruments when used in combination with the Seal mode are indicated for open, laparoscopic (including single-site surgery) general surgery and gynecological surgery (including urologic, thoracic, plastic and reconstructive, bowel resections, cholecystectomies, Nissen fundoplication, adhesiolysis, oophorectomy, hysterectomies (both vaginal assisted and abdominal) etc), and endoscopic surgery or in any procedure in which vessel sealing, coagulation, grasping is performed. These devices have been designed to seal vessels (up to and including 7 mm in diameter), **tissue bundles, and lymphatics**.

This mode is also indicated for open ENT procedures in adults for sealing of vessels, lymphatics and tissue bundles away from unintended thermally sensitive structures.

The THUNDERBEAT hand instruments have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

Compliance to Voluntary Standards

The design of the THUNDERBEAT TB-0535PC, 0545PC, 0510IC, 0520IC, 0535IC and 0545IC complies with the following standards:

AAMI/ ANSI60601-1: 2005/(R)2012 and CI:2009/(R)2012
IEC60601-1-1:2000
IEC60601-2-2:2009
IEC60601-1-2:2007
IEC60601-2-18: 2009
ISO10993-1:2009
ISO11135-1:2007
ISO14971:2007

Summary of Sterilization and Shelf Life Discussion

The sterilization had been tested to comply with ISO11135-1: 2007.

Real Time Aging testing confirmed that the subject devices have a three year shelf life.

Summary of Performance Testing

The following performance testing was conducted.

1. Bench Testing

Test #A: THUNDERBEAT Ex-vivo Sealing & Cutting Performance Confirmation Test on Blood Vessels

Test #B: THUNDERBEAT Ex-vivo Cutting Performance Confirmation Test on Blood Vessels and Mesentery.

Test #Fa: Sealing performance of the THUNDERBEAT SEAL & CUT mode

Test #Fb: Sealing performance and characteristic of the THUNDERBEAT SEAL & CUT mode during activation

Test #Fc: Sealing performance of the THUNDERBEAT SEAL & CUT mode

Test #H: Comparison of dissecting performance between the THUNDERBEAT vs. Control devices

Test #I/J: A comparison of heating at the grasping section of THUNDERBEAT Hand Instruments vs. Control devices.

Test #P: THUNDERBEAT Ex-vivo Sealing & Cutting and Sealing Performance - Histopathological Confirmation Test on Blood Vessels.

2. Animal Test

Test Ea: THUNDERBEAT In-vivo Sealing & Cutting and Sealing Performance Confirmation Testing on Porcine Blood Vessels, Lymphatics and Tissue Bundles.

Substantial Equivalence

The subject devices have identical technology, performance, dimensions and materials. The differences between the predicate and the subject devices are expanded indications for use and additional marketing claims. To support the proposed indications for use and marketing claims, the performance tests summarized above were conducted.

Conclusion:

In summary, the Gyrus ACMI THUNDERBEAT TB-0535PC, 0545PC, 0510IC, 0520IC, 0535IC and 0545IC handpieces are substantially equivalent to the predicate devices and present no new questions of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 19, 2014

OLYMPUS MEDICAL SYSTEMS CORPORATION
% Mr. Graham Baillie
Gyrus ACMI Incorporated
136 Turnpike Road
Southborough, Massachusetts 01772

Re: K132703
Trade/Device Name: Thunderbeat
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical, Cutting & Coagulation and Accessories
Regulatory Class: Class II
Product Code: GEI, LFL
Dated: April 16, 2014
Received: April 18, 2014

Dear Mr. Baillie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132703

Device Name
THUNDERBEAT TB-0535PC/0545PC/0510IC/0520IC/0535IC/0545IC

Indications for Use *(Describe)*
THUNDERBEAT TB-0535PC/0545PC/0535IC/0545IC

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THUNDERBEAT TB-0510IC/0520IC

The THUNDERBEAT hand instruments are intended to be used with the Ultrasonic Generator (USG-400), the Electrosurgical Generator (ESG-400), and the THUNDERBEAT Transducer, (TD-TB400).

Seal & Cut mode:
The THUNDERBEAT hand instruments when used in combination with the Seal & Cut mode are indicated for open, laparoscopic (including single-site surgery) general surgery and gynecological surgery (including urologic, thoracic, plastic and reconstructive, bowel resections, cholecystectomies, Nissen fundoplication, adhesiolysis, oophorectomy, hysterectomies (both vaginal assisted and abdominal) etc) and endoscopic surgery or in any procedure in which cutting, vessel ligation (sealing and cutting), coagulation, grasping, and dissection is performed. These devices have been designed to seal and cut vessels (up to and including 7 mm in diameter), tissue bundles, and lymphatics.

This mode is also indicated for open ENT procedures in adults for ligation (sealing and cutting) of vessels, lymphatics and tissue bundles away from unintended thermally sensitive structures.

Seal mode:
The THUNDERBEAT hand instruments when used in combination with the Seal mode are indicated for open,

laparoscopic (including single-site surgery) general surgery and gynecological surgery (including urologic, thoracic, plastic and reconstructive, bowel resections, cholecystectomies, Nissen fundoplication, adhesiolysis, oophorectomy, hysterectomies (both vaginal assisted and abdominal) etc), and endoscopic surgery or in any procedure in which vessel sealing, coagulation, grasping is performed. These devices have been designed to seal vessels (up to and including 7 mm in diameter), tissue bundles, and lymphatics.

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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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